Docket No.: 20022/42179
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Umberto Benatti et al.

Application No.: 10/584,874 | Confirmation No.: 7927

Filed: June 7, 2007 | Art Unit: 1654

For: Glutathione Derivatives and Their Uses for the Treatment of Viral Diseases | Examiner: R. T. Niebauer

REPLY BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This reply brief is submitted to respond to points of argument and to correct erroneous statements made in the Examiner's Answer dated June 8, 2010 to appellants' Appeal Brief.

Throughout the Examiner's Answer, the examiner relies upon column 4, lines 10-26 of U.S. Patent No. 5,464,825 ('825) for a teaching that the monoesters of the '825 patent are hydrolyzed to yield an N-acyl GSH (glutathione). The '825 patent is directed to providing compounds that are transported into cells such that GSH is generated *in vivo*. The portion of the '825 patent relied upon by the examiner illustrates the *in vivo* generation of GSH from a monoester of the '825 patent.

The examiner *neglects* the important features of the '825 patent compounds, i.e., that a *monoester* is required to achieve an increase in intracellular GSH levels. Comparative Example 1 of the '825 patent shows that GSH itself does not lead to increased intracellular GSH levels. GSH contains two carboxylic acid moieties (like the presently claimed compounds) and is free of an ester moiety. Accordingly, a prodrug as described in the '825 patent is needed for transport into the cells and conversion to GSH.

Appellants have found new compounds that are capable of increasing GSH levels and that are nonobvious over the compounds set forth in the '825 patent for the reasons set forth in appellants' Appeal Brief. In particular, the claimed compounds have structural features that are *discouraged* by the '825 patent.

In demonstrating the nonobviousness of the claimed compounds over the compounds of the '825 patent, appellants demonstrated the substantial differences in structure and the unpredictability of the art, including testing of compounds structurally more related to the claimed compounds than the compounds of the '825 patent that *failed* to increase GSH levels and/or that were toxic.

In the Examiner's Answer, the examiner often refers to the claims as failing to recite an element in the claims, such as use in cells[1]. Appellants provided reasoning and arguments showing the nonobviousness of the present *compound* claims based unexpected results and the unpredictability in art. It is axiomatic that inclusion of an intended use in a compound claims bears no weight in a patentability determination. The examiner's reliance upon *In re Van Geuns* therefore is misplaced. The compound claims fully recite all features of the compounds, without relying on any limitation in the specification. The features that the examiner contends should be present in the claims have been pointed out to show the nonobviousness of the present claims.

The examiner, at page 19, states that appellants concede predictability in art. This statement flies in the face of appellants' statements, pharmokinetics, and common sense. In the Appeal Brief, appellants merely stated that they *assume* the compounds of the '825 patent are efficacious, and that it would have been of no benefit to compare the claimed compounds to the compounds of the '825 patent because of the substantial difference in structure between the classes of compounds. Applicants clearly showed the unpredictability in the art in the specification by comparing the claimed compounds to compounds having a chain length different from butanoyl, as set forth in the appellants' Appeal Brief.

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[1] Page 8 of the Examiner's Answer, "With respect to use in cells, it is recited that claim 15 is drawn to a compound with no specific use recited in the claims. It is noted that features upon which Appellants rely (i.e., use in cells) are not recited in the rejected claim(s)." Also, page 11, page 15, and page 19 of the Examiner's Answer for example, wherein the examiner makes similar statements.

The examiner is apparently relying upon an "obvious to try" rationale to support the rejection. This rational requires choosing from a finite number of *identified predictable* solutions, with a reasonable expectation of success (MPEP §2141.III.). In this case, what can be considered an identifiable solution? The present claims actually have structural features discouraged by the '825 patent, so it cannot be stated that the '825 patent provides any identifiable solutions. The unpredictability in the art is clearly set forth in appellants' Appeal Brief. Accordingly, it is submitted that the examiner has failed to establish obviousness of the present claims based on an obvious-to-try rational.

Overall, the examiner has provided no further rationale to support a conclusion of obvious over the reasoning set forth in the Office Actions. Appellants fully addressed the examiner's reasoning in prior responses and in the Appeal Brief.

In summary, it is submitted that the examiner's final rejection of claims 15, 17, 18, and 23 should be reversed.

Dated: July 27, 2010

Respectfully submitted,

By_____

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